DETAILED ACTION

Application Status

Claims 47-56 are currently pending in this application.

In response to a previous Office action, a non-final action (mailed on July 15, 2010), Applicants filed an amendment on November 8, 2010, amending claims 47-55 that is acknowledged.

Claims 47-56 are under consideration and are present for examination.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jason R. Dinges, applicants' representative on January 12, 2011.

Amend claims as shown below:

Claim 47 (Currently Amended): A method of ~~treatment of~~ treating human liver, breast, colon or rectal ~~malignancies~~ cancer, comprising administering parenterally to a subject in need thereof a modified, full-length recombinant human arginase I polypeptide having an amino acid sequence encoded by a nucleic acid of SEQ ID NO: 8, which wherein said human arginase I is modified by ~~covalently linked~~ covalent linkage to at least one polyethylene glycol (PEG) molecule, wherein the administration of the modified, full-length recombinant human arginase I

polypeptide reduces the physiological arginine level in the subject to below 10 μM for at least 3 days.

Claim 48 (Currently Amended): A method of ~~treatment of~~ treating human liver, breast, colon or rectal ~~malignancies~~ cancer, comprising administering parenterally to a subject in need thereof a modified, full-length recombinant human arginase I polypeptide having the amino acid sequence of SEQ ID NO: 9, wherein said human arginase I modified by ~~covalently linked~~ covalent linkage to at least one polyethylene glycol (PEG) molecule, wherein the administration of the modified, full-length recombinant human arginase I polypeptide reduces the physiological arginine level in the subject to below 10 μM for at least 3 days.

Claim 49 (Currently Amended): A method of ~~treatment of~~ treating human liver, breast, colon or rectal ~~malignancies~~ cancer, comprising administering parenterally to a subject in need thereof a modified, full-length recombinant human arginase I polypeptide having an amino acid sequence encoded by a nucleic acid of SEQ ID NO: 2, wherein said human arginase I is modified by ~~covalently linked~~ covalent linkage to at least one polyethylene glycol (PEG) molecule, wherein the administration of the modified, full-length recombinant human arginase I polypeptide reduces the physiological arginine level in the subject to below 10 μM for at least 3 days.

Claim 50 (Currently Amended): A method of ~~treatment of~~ treating human liver, breast, colon or rectal ~~malignancies~~ cancer, comprising administering parenterally to a subject in need thereof a modified, full- length recombinant human arginase I polypeptide having the amino acid sequence of SEQ ID NO: 3, wherein said human arginase I is modified by ~~covalently linked~~ covalent linkage to at least one polyethylene glycol (PEG) molecule, wherein the administration of the

modified, full-length recombinant human arginase I polypeptide reduces the physiological arginine level in the subject to below 10 μM for at least 3 days.

Claim 51 (Currently Amended): A method of ~~treatment of~~ treating human liver, breast, colon or rectal ~~malignancies~~ cancer, comprising administering parenterally to a subject in need thereof a modified, full-length recombinant human arginase I polypeptide of 80-100% purity as determined by gel chromatography and densitometry having an amino acid sequence encoded by a nucleic acid of SEQ ID NO: 8, wherein said human arginase I is modified by ~~covalently linked~~ covalent linkage to at least one polyethylene glycol (PEG) molecule wherein the administration of the modified, full-length recombinant human arginase I polypeptide reduces the physiological arginine level in the subject to below 10 μM for at least 3 days.

Claim 52 (Currently Amended): A method of ~~treatment of~~ treating human liver, breast, colon or rectal ~~malignancies~~ cancer, comprising administering parenterally to a subject in need thereof a modified, full-length recombinant human arginase I polypeptide of 80-100% purity as determined by gel chromatography and densitometry, having the amino acid sequence of SEQ ID NO: 9, wherein said human arginase I is modified by ~~covalently linked~~ covalent linkage to at least one polyethylene glycol (PEG) molecule, wherein the administration of the modified, full-length recombinant human arginase I polypeptide reduces the physiological arginine level in the subject to below 10 μM for at least 3 days.

Claim 53 (Currently Amended): A method of ~~treatment of~~ treating human liver, breast, colon or rectal ~~malignancies~~ cancer, comprising administering parenterally to a subject in need thereof a modified, full-length recombinant human arginase I polypeptide of 80-100% purity as

determined by gel chromatography and densitometry having an amino acid sequence encoded by a nucleic acid of SEQ ID NO: 2, wherein said human arginase I is modified by ~~covalently linked~~ covalent linkage to at least one polyethylene glycol (PEG) molecule wherein the administration of the modified, full-length recombinant human arginase I polypeptide reduces the physiological arginine level in the subject to below 10 μM for at least 3 days.

Claim 54 (Currently Amended): A method of ~~treatment of~~ treating human liver, breast, colon or rectal ~~malignancies~~ cancer, comprising administering parenterally to a subject in need thereof a modified, full-length recombinant human arginase I polypeptide of 80-100% purity as determined by gel chromatography and densitometry having the amino acid sequence of SEQ ID NO: 3, wherein said human arginase I is modified by ~~covalently linked~~ covalent linkage to at least one polyethylene glycol (PEG) molecule wherein the administration of the modified, full-length recombinant human arginase I polypeptide reduces the physiological arginine level in the subject to below 10 μM for at least 3 days.

Claim 55 (Currently Amended): A method of ~~treatment of~~ treating human liver, breast, colon or rectal ~~malignancies~~ cancer, comprising administering parenterally to a subject in need thereof a modified, full-length recombinant human arginase I polypeptide comprising the amino acid sequence of SEQID NO: 3, which is of 80-100% purity, wherein said human arginase I is modified by ~~covalently linked~~ covalent linkage to at least one polyethylene glycol (PEG) molecule, and has an extended half-life of at least 3 days.

Allowable Subject Matter

Claims 47-56 are allowed.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The applicant has claimed a method of treating human liver, breast, colon or rectal cancer, comprising administering parenterally to a subject in need thereof a modified, full-length recombinant human arginase I polypeptide having an amino acid sequence encoded by a nucleic acid of SEQ ID NO: 8, which wherein said human arginase I is modified by covalent linkage to at least one polyethylene glycol (PEG) molecule, wherein the administration of the modified, full-length recombinant human arginase I polypeptide reduces the physiological arginine level in the subject to below 10 μM for at least 3 days. A standard search did not produce any prior art that suggests or teaches the claimed invention. The claimed invention is novel and nonobvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, whose telephone number is (571) 272-8137. The examiner can normally be reached on Monday-Friday from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/ANAND U DESAI/
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